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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/661,927	09/14/2000	William J. Dower	019282-000110US	1158

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EXAMINER
TIZIO, STEVEN C

ART UNIT	PAPER NUMBER
1627	5

DATE MAILED: 12/18/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)	
Office Action Summary	09/661,927	DOWER ET AL.	
Restriction/Election Only	**Examiner**	**Art Unit**	
	Steven C Tizio	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-137* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-137* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Please note: *In an effort to enhance communication with our customers and reduce processing time, Group 1627 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is* ***(703) 305-3704****. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this pilot program. If you have any questions or suggestions please contact Jyothnsa Venkat, Ph.D., Supervisory Examiner, at Jyothsna.Venkat@uspto.gov or 703-308-2439. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.*

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-68, drawn to the method of screening for a carrier-type transport protein and/or a ligand, classified in class 435, subclass 7.1 or DIG 14.

   II. Claims 69-74, drawn to the method of screening for a carrier-type transport protein and/or a substrate, classified in class 435, subclass 7.1 or DIG 14.

III. Claim 75, drawn to the method of screening for a carrier-type transport protein and/or a ligand, classified in class 435, subclass 7.1 or DIG 14.

IV. Claim 76, drawn to the method of screening for a carrier-type transport protein and/or a ligand, classified in class 435, subclass 7.1 or DIG 14.

V. Claim 77, drawn to the method of screening for a carrier-type transport protein and/or a substrate, classified in class 435, subclass 7.1 or DIG 14.

VI. Claims 78-106, drawn to the method of screening for a receptor-type transport protein and/or a ligand, classified in class 435, subclass 7.1 or DIG 14.

VII. Claims 107-126, drawn to the method of screening for a substrate of a transport protein, classified in class 435, subclass 7.1 or DIG 14.

VIII. Claims 127-137, drawn to the pharmaceutical composition, classified in class 424, subclass 400+.

2. The inventions are distinct, each from the other because of the following reasons:

3. **Groups I-VIII** represent separate and distinct inventions. **Groups I-VIII** are drawn to different methods and a product (i.e., e.g., which are directed to different purposes, use different materials, recite different method or process steps for the preparation of different product(s), screening of different characteristics, such as different binding affinities, different biochemical reaction conditions, etc. or lead to different final results). Therefore, the groups that describe these processes and

products have different issues regarding patentability and enablement, and represent patentably distinct subject matter, which merits separate and burdensome searches. Art anticipating or rendering obvious each of the above-identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing features and/or characteristics. Each group will support separate patents.

4. Inventions of **Groups I-V** and **Group VI** are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different screening methods in that the inventions of **Groups I-V** relate to screening for a carrier-type transport protein and the invention of **Group VI** relates to a method that screens for a receptor-type transport of protein. The specification (in page 1, lines 26-33, page 2; lines 1-12) discloses that the carrier-type transport protein described in **Groups I-V** uses a method of "ferrying" compounds across cell membranes via cell membrane-anchored proteins whereas the receptor-type transport protein described in **Group VI** uses a method of invagination and encapsulation to create transport vesicles in order to transport various compounds into cells.

5. Inventions of **Groups I, III, IV** and of **Groups II, V** are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and

they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions of **Groups I,III,IV** and **Groups II,V** are drawn to different screening methods. The inventions of **Groups I, III, IV** describe a method of screening for a carrier-type transport protein and/or a ligand whereas **Groups II and V** describe a method of screening for a carrier-type transport protein and/or a substrate. The specification (in page 10, lines 19-34), discloses "a 'substrate' of a transport protein is a compound whose uptake into or passage through a cell is facilitated by the transport protein and a 'ligand' of a transport protein includes substrates and other compounds that bind to the transport protein without being taken up or transported through a cell." Thus, restriction between the groups is proper.

6. Inventions of **Groups II and V** and of **Group VII** are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different screening methods in which the method of **Groups II and V** are used to screen for a transport protein and/or a substrate whereas the screening method of **Group VII** is used to just screen for a substrate. A substrate can consist of many different organic and inorganic molecules including peptides and proteins.

7. Inventions of **Groups I-VII** and **Group VIII** are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and

they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of **Groups I-VII** are drawn to different methods, which do not use the pharmaceutical composition of **Group VIII**. Thus, restriction between the groups is proper.

Election of Species

8. This application contains claims directed to the following patentably distinct species of the claimed invention:

A) if **Group I** is elected, applicants are requested to elect a single species for each of the following:

(1) elect a single species of signal from the reporter of a complex

(2) elect a single species of morphological change

(3) elect a single species of agent

(4) elect a single species of compound

(5) elect a single species of reporter (i.e. a fluorophore and quencher moiety in **claim 6**)

(6) elect a single species of cell (i.e. Chinese hamster ovary (CHO) cell in **claim 53**; test cells and counterpart control cells in **claim 26**)

(7) elect a single species of distinguishable characteristics of cells

(8) elect a single species of cellular morphology

(9) elect a single species of marker on the surface of cells

(10) elect a single species of epitope including the antibodies specific for the different epitopes and the labels of the epitopes in **claim 32**

(11) elect a single species of labels (i.e. radiolabel, **claim 38**)

(12) elect a single species of enzyme substrate in **claim 39**

(13) elect a single species of pharmaceutical agent

(14) elect a single species of complex and modified complex

(15) elect a single species of carrier-type transport protein (i.e. amino acid transporter, PEPT1)

(16) elect a single species of endogenous proteins

(17) elect a single species of test compound

(18) elect a single species of linker

(19) elect a single species of detection step

(20) elect a single species of small molecule

(21) elect a single species of peptide

B) if **Group II** is elected, applicants are requested to elect a single species of the following:

(1) elect a single species of cells

(2) elect a single species of carrier-type transport protein

(3) elect a single species of compound

(4) elect a single species of reporter (i.e. fluorophore and quencher moiety in **claim 70**)

(5) elect a single species of substrate

(6) elect a single species of signal

(7) elect a single species of complex

C) if **Group III** is elected, applicants are requested to elect a single species of the following:

(1) elect a single species of cells

(2) elect a singe species of carrier-type transport protein

(3) elect a single species of distinguishable characteristics

(4) elect a single species of complex

(5) elect a single species of compound

(6) elect a single species of reporter

(7) elect a single species of signal

D) if **Group IV** is elected, applicants are requested to elect a single species of the following:

(1) elect a single species of cells

(2) elect a single species of carrier-type transport protein

(3) elect a single species of complex

(4) elect a single species of compound

(5) elect a single species of reporter

(6) elect a single species of signal

E) if **Group V** is elected, applicants are requested to elect a single species of the following:

(1) elect a single species of cells

(2) elect a single species of carrier-type transport protein

(3) elect a single species of complex

(4) elect a singe species compound

(5) elect a single species of reporter

(6) elect a single species of signal

(7) elect a single species of substrate

(8) elect a single species of pharmaceutical agent

(9) elect a single species of modified complex

F) if **Group VI** is elected, applicants are requested to elect a single species of the following:

(1) elect a single species of complex

(2) elect a single species of compound

(3) elect a single species of reporter (i.e. fluorophore and a quencher moiety in **claim 79**)

(4) elect a single species of cells

(5) elect a single species of receptor-type transport proteins

(6) elect a single species of signal

(7) elect a single species of ligand

(8) elect a single species of distinguishable characteristics

(9) elect a single species of support

(10) elect a single species of tag

(11) elect a single species of human intestinal epithelium transport protein

(12) elect a single species of optical signal

(13) elect a single species of substrate

(14) elect a single species of enzyme

(15) elect a single species of membrane

(16) elect a single species of metabolic event

(17) elect a single species of indicator cells

(18) elect a single species of body compartment

(19) elect a single species of tissue

(20) elect a single species of animal

G) if **Group VII** is elected, applicants are requested to elect a single species of the following:

(1) elect a single species of body compartment

(2) elect a single species of animal

(3) elect a single species of complex

(4) elect a single species of support

(5) elect a single species of test compound

(6) elect a single species of reporter (i.e. a capture tag in **claim 113**)

(7) elect a single species of recovering step (i.e. using FACS sorting in **claim 114**)

(8) elect a single species of encoding tag

(9) elect a specific synthesis step in **claim 116**

(10) elect a specific decoding of the encoding tag in **claim 116**

(11) elect a single species of polarized cells

(12) elect a single species of transport proteins

(13) elect a single species of a monolayer of cells

(14) elect a single species of substrate

(15) elect a single species of receptor-type transport protein

(16) elect a single species of receptor

(17) elect a single species of optically detectable signal

(18) elect a single species of fluorescent molecule

H) if **Group VIII** is elected, applicants are requested to elect a single species of the following:

(1) elect a single species of nanoparticle

(2) elect a single species of drug

(3) elect a single species of ligand

(4) elect a single species of receptor-type transport proteins

(5) elect a single species of pharmaceutical composition

(6) elect a single species of substrate

(7) elect a single species of first cellular receptor

(8) elect a single species of transport protein

(9) elect a single species of a cell

(10) elect a single species of a second transport protein

(11) elect a single species of an agent

(12) elect a single species of a compound

(13) elect a single species of a target organelle.

9. The different species claimed are distinct from each other because they are structurally and functionally different and do not require the other for ultimate use, the species election for examination purposed as indicated is proper.

10. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, **claims 1-31, 33-38, 40-115, and 117-137** are generic.

11. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

12. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

13. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

14. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

16. Applicant is required to reply to this restriction requirement within 30 days of mailing this action. See MPEP 809.2(a).

Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Tizio whose telephone number is (703) 305-1903. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached at (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

PADMASHRI PONNALURI
PRIMARY EXAMINER

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